UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. BIONPHARMA INC., Defendant	)	Civil Action No. 21-12870 (MAS) (DEA) **Motion Returnable: August 16, 2021** **ORAL ARGUMENT REQUESTED**

DEFENDANT BIONPHARMA'S BRIEF IN SUPPORT OF ITS MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a)

Of Counsel:

Andrew M. Alul
Roshan P. Shrestha, Ph.D.
TAFT, STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
(312) 527-4000

Thomas R. Curtin
George C. Jones
MCELROY, DEUTSCH, MULVANEY & CARPENTER, LLP
1300 Mount Kemble Ave.
P.O. Box 2075
Morristown, NJ 07962-2075
(973) 993-8100

Attorneys for Defendant Bionpharma Inc.

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
’008 patent	U.S. Patent No. 9,669,008 B1
’023 patent or patent-in-suit	U.S. Patent No. 11,040,023 B2
’442 patent	U.S. Patent No. 9,808,442 B2
’482 patent	U.S. Patent No. 10,786,482 B2
’587 application	U.S. Patent Application No. 17/150,587, the prosecution history of which is attached as Ex. V to the Shrestha Declaration
’621 patent	U.S. Patent No. 10,918,621 B2
’745 patent	U.S. Patent No. 10,039,745 B2
’868 patent	U.S. Patent No. 10,772,868 B2
’987 patent	U.S. Patent No. 10,154,987 B2
Amneal	Amneal Pharmaceuticals LLC
ANDA	Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j)
Azurity	Plaintiff Azurity Pharmaceuticals, Inc., successor-in-interest to Silvergate Pharmaceuticals, Inc.
Azurity’s enalapril liquid patent family	’008, ’442, ’745, ’987, ’482, ’868,’621, and ’023 patents
Bionpharma	Defendant Bionpharma Inc.
Bionpharma’s ANDA	Bionpharma’s ANDA No. 212408
Bionpharma’s Motion to Dismiss or Bionpharma’s MTD	Defendant Bionpharma’s Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6), submitted concurrently herewith
Bionpharma’s Motion to Dismiss Brief or Bionpharma’s MTD Br.	Defendant Bionpharma’s Brief in Support of Its Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6), submitted concurrently herewith
The common specification	The common specification of Azurity’s enalapril liquid patent family

Abbreviation	Meaning
DOE	Doctrine of equivalence
Epaned® Kit	Azurity's predecessor product to Epaned® (*see* Shrestha Decl. Ex. G, Op. 7)
First Wave Patents	'008, '442, '745, and '987 patents
First Wave Suits	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.)
NDA	New Drug Application pursuant to 21 U.S.C. § 355(b)(1)
Paragraph IV certification	Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
PI	Preliminary injunction
POSA	Person of ordinary skill in the art
PTO or Patent Office	United States Patent and Trademark Office
Second Wave Patents	'868, '482, and '621 patents
Second Wave Suit	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.)
Shrestha Decl.	The Declaration of Roshan P. Shrestha, Ph.D., submitted concurrently herewith
Third Wave Suit	The instant action, *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-12870 (D.N.J.)

Defendant Bionpharma respectfully submits the instant Brief in Support of Its Motion to Transfer Venue Pursuant to 28 U.S.C. § 1404(a).

INTRODUCTION

This action represents the third wave in a series of lawsuits filed by Plaintiff Azurity against Bionpharma asserting that Bionpharma's ANDA No. 212408—which seeks FDA approval to market a 1 mg/ml enalapril maleate oral solution as generic to Silvergate's Epaned® antihypertensive prescription drug product—infringes Azurity's enalapril oral liquid patent family. The First[1] and Second Wave[2] Suits were filed in Delaware Federal Court, where the parties have spent over two and a half years litigating seven patents that are in the same family as the '023 patent that is the subject of the instant Third Wave Suit Chief Judge Stark held a 5-day bench trial in the First Wave Suits on February 1-5, 2021. On April 27, 2021, Judge Stark issued a 72-page opinion finding that Azurity failed to prove infringement—including because Azurity failed to prove that Bionpharma's ANDA product contained a buffer—and, on April 29, 2021, entered judgment in Bionpharma's favor. Judge Stark's decision in the First Wave Suits rendered moot Azurity's Second Wave Suit on collateral estoppel grounds, because all claims of the Second Wave Patents require a buffer, and the Second Wave Suit was dismissed on May 21, 2021 with prejudice, unless Azurity secures a decision on appeal of the First Wave Suits that eliminates the estoppel.

In an effort to get away from Judge Stark and His Honor's findings and rulings in connection with the First and Second Wave Suits, including His Honor's finding that Azurity's expert in those suits lacked credibility, Azurity has filed the instant Third Wave Suit here in New Jersey alleging infringement of the newly issued '023 patent, which is in the same family as the

[1] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.).

[2] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.).

First and Second Wave Patents, and which contains claims that, as explained in Bionpharma's concurrently filed Motion to Dismiss papers, are patentably indistinct from the claims of the First and Second Wave Patents that Bionpharma defeated in connection with the First and Second Wave Suits.

Bionpharma respectfully submits that Azurity's blatant forum shopping should be rejected, and that this case should be transferred to the District of Delaware for the following reasons:

1. **The First-Filed Rule**, which gives this Court the power to enjoin a proceeding involving the same parties and issues already before another district court, warrants transfer to Delaware because Azurity filed the related First and Second Wave Suits in Delaware before the instant Third Wave Suit, and Azurity should be held to its original forum choice.

2. **28 U.S.C. § 1404(a)—Delaware Is a More Convenient Forum**:

2.a. **Public Interest Factors**: The public interest factors specified in *Jumara v. State Farm Insurance Company*, 55 F.3d 873 (3d Cir. 1995) strongly support transfer to Delaware, where Azurity has already sued Bionpharma ***three times*** on related patents involving the same ANDA at issue here (culminating in a trial and decision rendered by Chief Judge Stark less than three months ago), and where there were ***five related pending suits*** that Azurity filed against other enalapril oral solution ANDA-filers involving the same family of patents, three of which are still pending.[3]

Moreover, Judge Stark is in the ***best position*** to assess and rule on Bionpharma's concurrently filed Motion to Dismiss, which is based on claim preclusion grounds. Resolution of Bionpharma's Motion to Dismiss will require a comparison of the meaning and scope of the claims of the patents adjudicated not infringed by Judge Stark in the First Wave Suits—something which Judge Stark has already ruled on—with the meaning and scope of the claims of the related patent-in-suit. *See, e.g., SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018).

2.b. **Private Interest Factors**: The *Jumara* private interest factors also strongly support transfer, as both parties to this action reside in Delaware, and as thousands of pages of documents relevant to the resolution of the instant action are already before the Delaware court.

For the foregoing reasons, explained more fully before, Bionpharma respectfully requests that the instant action be transferred to the District of Delaware.

[3] Inexplicably, Azurity failed to designate the instant Third Wave Suit as related to at least the three pending related suits in Delaware. *See* ECF No. 1-2, Civil Cover Sheet.

FACTUAL BACKGROUND

I. THE FIRST WAVE SUITS

Bionpharma filed its ANDA back in 2018, seeking approval from FDA to market its ANDA product as generic to Azurity's Epaned®. ECF No. 1, Compl. ¶ 14. In response, Azurity filed the First Wave Suits starting in December of 2018 in Delaware Federal court, asserting that Bionpharma's ANDA and the product described therein infringe Azurity's '008, '442, '745, and '987 patents ("First Wave Patents"). Shrestha Decl. Exs. A and B, First Wave Suits Complaints. The claims of Azurity's First Wave Patents are directed to: (1) a group of enalapril liquid formulations that contain citric acid and sodium citrate as a buffer system at specific concentrations, sodium benzoate as a preservative at specific concentrations, and that are stable for 12 months at refrigerated conditions; and (2) methods of treatment using those liquids. *Id*. at Exs. C-F, First Wave Patents at claims; *id*. at Ex. G, Op. at 15-19. Bionpharma had designed its ANDA product extensively around Azurity's First Wave Patents, including by omitting a buffer entirely, and by utilizing an alternative to the claimed sodium benzoate preservative. Shrestha Decl. Ex. G, Op. at 7-9.

The Delaware court held a five day bench trial on February 1-5, 2021 and, on April 27, 2021, issued its Opinion finding the asserted claims of Azurity's First Wave Patents not infringed by Bionpharma's ANDA product, including because Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product, and because the alternative to the claimed sodium benzoate preservative that Bionpharma used in its ANDA product was disclosed in the common specification of the First Wave Patents, but not claimed, and was therefore dedicated to the public. *Id*. at 1, 64-66, 68-71. The Court entered final judgement in Bionpharma's favor shortly thereafter, which Azurity has appealed. Shrestha Decl. Ex. H, Final J.; *id*. at Ex. I, Notice of Appeal. Those

appeals are currently pending. *See Azurity Pharm., Inc. v. Bionpharma Inc.*, Nos. 2021-1926, -1927 (Fed. Cir.).

II. THE SECOND WAVE SUIT

Shortly after Bionpharma filed its ANDA, Azurity began filing patent applications seeking considerably broader and different claim coverage, and eventually secured issuance of the '868, '482, and '621 patents ("Second Wave Patents") in late 2020 and early 2021, which were the subject of Azurity's Second Wave Suit. Shrestha Decl. Ex. J, Second Wave Suit, ECF No. 49, Second Am. Compl.; *id*. at Exs. K-M, Second Wave Patents at covers. Concerned about the potential outcome of the First Wave Suits and the April 30, 2021 expiration of the 30-month stay, on March 31, 2021, Azurity moved the Delaware court for a preliminary injunction in connection with the Second Wave Suit. *Id*. at Ex. N, Mot. for Prelim. Inj. The parties fully briefed Azurity's PI motion, filing thousands of pages of briefing, expert declarations, and documentary evidence in connection with the motion. *See* Second Wave Suit, ECF Nos. 67-71, 77-79, 84-87.

As explained above, on April 27, 2021, just two days before the hearing scheduled on Azurity's PI motion (Second Wave Suit, ECF No. 58), the Delaware court issued its opinion in the First Wave Suits finding that, *inter alia*, Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product. Because all of the claims of the Second Wave Patents require a buffer (Shrestha Decl. Exs. K-M, Second Wave Patents at claims), the Delaware court's finding that Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product rendered moot Azurity's Second Wave Suit and PI motion on collateral estoppel grounds, and the parties stipulated to dismissal of the Second Wave Suit, which was so ordered on May 21, 2021. *Id*. at Ex. O, Joint Stipulation for Dismissal ("JSD"); Second Wave Suit, May 21, 2021 docket entry. By the express terms of the dismissal order, all claims of the Second Wave Suit were dismissed with prejudice, except in the event "that the Federal Circuit renders a decision whereby collateral

estoppel would not apply to bar [Azurity's] assertion of the Second Wave Patents against Bionpharma." Shrestha Decl. Ex. O, JSD at 3.

III. THE INSTANT (THIRD WAVE) SUIT

On January 15, 2021, over two years after Bionpharma filed its ANDA with FDA and the commencement of the First Wave Suits, Azurity filed with the PTO U.S. Patent Application No. 17/150,587, which claims priority to the First and Second Wave Patents. ECF No. 1-1, Compl. Ex. A, '023 patent at cover. On June 22, 2021, the '587 application issued into the '023 patent, and Azurity instituted this Third Wave Suit that same day. ECF No. 1, Compl. The claims of the '023 patent are very similar to the claims of the First and Second Wave Patents, with the only difference being that the enalapril liquid formulations claimed in the '023 patent may contain, but do not explicitly require, a buffer. ECF No. 1-1, Compl. Ex. A, '023 patent at claims; Bionpharma's MTD Br. at 11-20.

IV. OTHER RELATED ENALAPRIL ANDA SUITS PENDING IN DELAWARE

The First and Second Wave Suits are not the only suits in Delaware that Azurity has instituted involving ANDAs for generic enalapril maleate liquids and Azurity's enalapril liquid patent family. Azurity has instituted the following suits involving the First and Second Wave Patents and ANDAs for generic enalapril liquids:

Silvergate Pharm., Inc. v. Amneal Pharm. LLC, C.A. 19-678-LPS (D. Del.)

Azurity Pharm, Inc. v. Annora Pharma Private Ltd., C.A. No. 19-753-LPS (D. Del.)

Azurity Pharm, Inc. v. Alkem Labs. Ltd., C.A. No. 19-2100-LPS (D. Del.)

Silvergate Pharm., Inc. v. Amneal Pharm. LLC, C.A. 20-1255-LPS (D. Del.)

Azurity Pharm, Inc. v. Annora Pharma Private Ltd., C.A. No. 21-196-LPS (D. Del.)

All but the 19-678 and 20-1255 remain pending.[4] Like the First and Second Wave Suits that were filed against Bionpharma in Delaware, and like the instant Third Wave Suit, these five suits involve(d) ANDAs seeking FDA approval of enalapril maleate oral liquids as generic to Azurity's Epaned® and Azurity's enalapril liquid patent family. Shrestha Decl. Ex. P, D. Del. 19-678 Compl.; *id*. at Ex. Q, D. Del. 19-2100 Compl.; *id*. at Ex. R, D. Del. 19-753 Compl.; *id*. at Ex. S, D. Del. 20-1255 Am. Compl.; *id*. at Ex. T, D. Del. 21-196 Compl. All of these lawsuits are or were pending before Chief Judge Stark, who presided over the First and Second Wave Suits against Bionpharma.

ARGUMENT

I. LEGAL STANDARD

A. The First-Filed Rule

The first-filed rule provides that "in all cases of federal concurrent jurisdiction, the court which first has possession of the subject must decide it." *EEOC v. Univ. of Pa.*, 850 F.2d 969, 971 (3d Cir. 1988) (internal brackets and quotations omitted). The first-filed rule "encourages sound judicial administration and promotes comity among federal courts of equal rank" and "gives a court 'the power' to enjoin the subsequent prosecution of proceedings involving the same parties and the same issues already before another district court." *Id*. Courts in this Circuit typically hold that "if the first-filed rule applies, there is a presumption that the later-filed action should be transferred or stayed." *See Landau v. Viridian Energy PA LLC*, 274 F. Supp. 3d 329, 333 (E.D. Pa. 2017) (citing *Koresko v. Nationwide Life Ins. Co.*, 403 F.Supp.2d 394, 403 (E.D. Pa. 2005)). In deciding whether to transfer, courts consider the same factors applicable to a motion to transfer

[4] The 19-678 and 20-1255 suits against Amneal were dismissed on June 29, 2021.

under § 1404(a). *Wheaton Indus., Inc. v. Aalto Sci., Ltd.*, C.A. No. 12-6965, 2013 WL 4500321, at *2 (D.N.J. Aug. 21, 2013).

B. 28 U.S.C. § 1404(a)

Even if the first-filed rule does not apply, a case may be transferred pursuant to § 1404(a). *Coyoy v. United States*, Civ. No. 20-2501 (KM) (ESK), 2021 WL 1050198, at 10 (D.N.J. Mar. 18, 2021). Pursuant to § 1404(a), a district court may transfer a civil action to another district where the action may have been brought "[f]or the convenience of parties and witnesses, in the interest of justice." "The purpose of Section 1404(a) is to prevent the waste of time, energy and money and to protect litigants, witnesses and the public against unnecessary inconvenience and expense." *Wm. H. McGee & Co. v. United Arab Shipping Co.*, 6 F. Supp. 2d 283, 287 (D.N.J. 1997) (citations and quotation marks omitted). The Third Circuit has articulated a list of twelve public and private interest factors for the district courts to consider when weighing whether an action should be transferred. *See Jumara*, 55 F.3d at 879-80.

II. THE INSTANT THIRD WAVE SUIT SHOULD BE TRANSFERRED TO DELAWARE

Azurity filed the instant Third Wave Suit here for one reason and one reason only: to get away from Chief Judge Stark in Delaware and his adverse judgment and findings in connection with the First and Second Wave Suits. There is simply no other rational explanation for why this suit is here given that Azurity has filed nine suits and multiple amended complaints against enalapril liquid ANDA filers asserting its enalapril liquid patent family, and all but the instant suit were filed in Delaware. This is clear instance of forum shopping and an attempt by Azurity to secure a new judge and a clean slate, and to get away from adverse rulings and findings (including that its expert in the First and Second Wave Suits lacked credibility (Shrestha Decl. Ex. G, Op. at 66 n.12)), and from positions taken by Azurity and its expert in the First and Second Wave Suits

that will pose problems for Azurity in the instant Third Wave Suit. Azurity's attempt at forum shopping should be rejected, as the first-filed rule warrants transfer to Delaware where Chief Judge Stark has presided over litigation between the parties involving Bionpharma's ANDA and Azurity's enalapril liquid patent family for over the last two and a half years, and because transfer would serve the public and private interests underlying § 1404(a).

A. Delaware Is a Proper Forum

Bionpharma is incorporated in Delaware, and is thus subject to personal jurisdiction there and venue is also proper there. ECF No. 1, Compl. ¶ 4; 28 U.S.C. § 1400(b). Azurity also resides in Delaware. ECF No. 1, Compl. ¶ 2; *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, 978 F.3d 1374, 1375 (Fed. Cir. 2020). Moreover, the parties have already been litigating for over the last two and a half years three suits Azurity has filed against Bionpharma in Delaware involving the same ANDA and the same patent family. Thus, there can be no dispute that Delaware is a proper forum for this action.

B. The First-Filed Rule Supports Transfer

"In determining the applicability of the first-filed rule, courts in the Third Circuit examine the chronology of the actions in addition to the overlapping subject matter issues, claims, and parties." *Worthington v. Bayer Healthcare LLC*, C.A. No. 11-2793 (ES), 2012 WL 1079716, at *3 (D.N.J. Mar. 30, 2012).

With respect to chronology, it is indisputable that Azurity filed the First and Second Wave Actions before the instant Third Wave Action. Moreover, Azurity should not be able to avoid the first-filed rule just because the First Wave Suits are on appeal and the Second Wave Suit has been dismissed. *See Chavez v. Dole Food Co.*, 796 F.3d 261, 266 (3d Cir. 2015), *vacated on other grounds*, 836 F.3d 205 (3d Cir. 2016) (that the first action was on appeal at the time the second action was dismissed did not render the first-file rule inapplicable). The Federal Circuit could

remand the First Wave Suits back to the Delaware court. Moreover, as explained above, if the Federal Circuit rules in the appeal of the First Wave Suits in a way that removes collateral estoppel, by the express terms of the dismissal order, Azurity might try to revive the Second Wave Suit. And that Azurity itself instituted the First and Second Wave Suits and the instant Third Wave Suit also does not negate application of the first-filed rule. *Id*. at 269 ("There is no authority, however, which holds that the first-filed rule only applies in cases where the filings are initiated by different parties.").

Regarding overlapping subject matter, issues, and parties, there can be no dispute that the same parties to this action are the parties involved in the First and Second Wave Suits filed in Delaware. And the subject matter and claims are the same (as explained in detail in Bionpharma's concurrently filed MTD Brief).[5] The First Wave and Second Wave Suits and the instant Third Wave Suit involve the same ANDA—Bionpharma's ANDA for a generic 1 mg/mL enalapril maleate oral solution—and Azurity's claims that that ANDA and the product described therein infringe Azurity's enalapril liquid patent family.

For these reasons, the first-filed rule applies, and the instant Third Wave Suit should be transferred to Delaware.

C. Transfer Is Warranted under § 1404(a)

As explained below, Delaware is a more convenient and appropriate forum for the instant Third Wave Suit as both the public and private interest factors enunciated in *Jumara* support transfer.

[5] Bionpharma acknowledges that "courts in the Third Circuit disagree as to the required extent of overlap between the earlier and later filed matters." *Coyoy*, 2021 WL 1050198, at *9-*10. Nevertheless, Bionpharma respectfully submits that, under either the "truly duplicative" or the relaxed "substantial overlap" test, *id*. at *9, the instant Third Wave Suit involves the "'same issues' already before [the District of Delaware]," warranting application of the first-filed rule, *EEOC*, 850 F.2d at 971.

1. The Public Interest Factors Strongly Support Transfer

The public interest factors include:

> 1) the enforceability of the judgment; 2) practical considerations that could make the trial easy, expeditious, or inexpensive; 3) the relative administrative difficulty in the two fora resulting from court congestion; 4) the local interest in deciding local controversies at home; 5) the public policies of the fora; and 6) the familiarity of the trial judge with the applicable state law in diversity cases.

S. Jersey Gas Co. v. Antero Res. Appalachian Corp., No. 15-CV-1888, 2016 WL 266340, at *3 (D.N.J. Jan. 21, 2016) (quoting *Jumara*, 55 F.3d at 879-80)

a. Enforceability of Judgment

This factor is neutral, as both Bionpharma and Azurity reside in Delaware (ECF No. 1, Compl. ¶¶ 2-4), and a judgment can be enforced against either party there and here.

b. Practical Considerations

i. Chief Judge Stark Has Spent over 2.5 Years Presiding over the Subject Matter of the Instant Third Wave Suit

"When related actions are pending in the transferee forum, the interest of justice is generally thought to 'weigh heavily' in favor of transfer." *Samsung Elecs. Co. v. Rambus, Inc.*, 386 F. Supp. 2d 708, 721 (E.D. Va. 2005). As explained above, the parties have been litigating Bionpharma's ANDA and Azurity's enalapril liquid patent family for over the past two and a half years in Delaware before Chief Judge Stark. Judge Stark is already intimately familiar with the facts and legal questions underlying this lawsuit. For over two and a half years, Judge Stark sifted through massive discovery, adjudicated discovery disputes, ruled on various dispositive motions, held a five day bench trial on infringement and invalidity[6] of Azurity's enalapril liquid patent

[6] The First Wave Suits were consolidated for trial with a related co-pending action Azurity filed against ANDA-filer Amneal Pharmaceuticals LLC (C.A. No. 19-678 (D. Del.)). Shrestha Decl. Ex. G, Op. at 1 n.2. Although Bionpharma did not raise an invalidity defense at trial, Amneal did, asserting both obviousness and lack of written description defenses against Azurity's First Wave

family, and issued a 72-page opinion finding that Bionpharma's ANDA and ANDA product do not infringe Azurity's First Wave Patents. At trial, Judge Stark heard extensive testimony and received into evidence thousands of pages of trial exhibits on:

> (1) Bionpharma's ANDA product, its composition, relevant properties including pH and stability, and proposed labeling (Shrestha Decl. Ex. G, Op. at 7-9);
>
> (2) Azurity's First Wave Patents, including their prosecution history, common specification, and claim scope (*id*. at 15-25);
>
> (3) Azurity's Epaned® product, its composition, proposed labeling, and relevant properties such as pH and stability (*id*. at 6-7);
>
> (4) background technical information regarding acid-base chemistry, buffers, and pharmaceutical oral liquid formulations, including their composition, preparation, and relevant properties such as formulation pH and stability (*id*. at 9-15); and
>
> (5) the prior art to Azurity's enalapril liquid patent family, including what was known about enalapril and oral liquid formulations comprising same, and prior art enalapril oral liquid formulations such as Azurity's Epaned® Kit predecessor product (*e.g.*, *id*. at 7).

Much, if not all, of this evidence that was heard by Judge Stark at trial in the First Wave Suits is going to be directly relevant to the issues that will be litigated in the instant Third Wave Suit, and many of Judge Stark's findings and rulings with respect to certain issues litigated in the First Wave Suits may have preclusive effect (*i.e.*, collateral estoppel) on issues to be decided in the instant case.

Yang v. Odom, 409 F. Supp. 2d 599 (D.N.J. 2006), a decision from a court in this District, is on point factually and legally. *Yang* involved a securities fraud action filed in this District and a 1404(a) motion filed by the defendants to transfer the New Jersey action to Federal court in Georgia, where twenty-three related class action securities fraud cases had previously been filed against the defendants, which were ultimately resolved in the defendants' favor. *Yang*, 409 F.

Patents. First Wave Suits, ECF No. 170, Final Pretrial Order Ex. 3(b), Amneal's Statement of Issues of Fact that Remain to Be Litigated.

Supp. 2d at 600-602. The *Yang* court recognized that "[i]t would be a gross waste of judicial resources for this Court to litigate the merits of Plaintiffs' claims from scratch," where, "[f]or over three years, [the Georgia court] sifted through the extensive evidence, expert testimony, and massive discovery" and "ruled on various dispositive motions and other legal issues in a matter substantially identical to the one before this Court." *Id*. at 608. Similarly, it would be a gross waste of resources for this Court to litigate this dispute from scratch, when Chief Judge Stark "has [already] expended enormous judicial resources and has become quite familiar with the issues presented by [Azurity's Complaint]." *Samsung*, 386 F. Supp. 2d at 722. "Judicial economy and the interest of justice favor a venue which has already committed judicial resources to the contested issues and is familiar with the facts of the case." *Id*.; *see also Teva Pharm. USA, Inc. v. Sandoz Inc.*, C.A. No. 17-275(FLW), 2017 WL 2269979, at *8-*10 (D.N.J. May 23, 2017) (case transferred to Delaware "where related, but not identical, cases are already pending"); *Job Haines Home for the Aged v. Young*, 936 F. Supp. 223, 233-34 (D.N.J. 1996) (finding that where judge in proposed transferee district was "intimately familiar" with the case at hand, it would be a "gross waste of judicial resources" not to transfer).

ii. Chief Judge Stark Is in the Best Position to Rule on Bionpharma's MTD

Concurrently filed herewith is Bionpharma's Motion to Dismiss where Bionpharma has moved this Court pursuant to Fed. R. Civ. P. 12(b)(6) for dismissal of Azurity's Complaint in the instant Third Wave Suit on claim preclusion grounds. As explained in Bionpharma's Motion to Dismiss Brief, Azurity is asserting the same cause of action in the instant Third Wave Suit that was previously litigated by the parties in connection with the First and Second Wave Suits, and Judge Stark's Final Judgment of non-infringement in the First Wave Suits, and the dismissal with prejudice of the Second Wave Suit, therefore preclude Azurity's infringement claims in the instant

Third Wave Suit as a matter of law. Bionpharma's MTD Br. at 7-20; *see also SimpleAir*, 884 F.3d at 1165-69. The court deciding Bionpharma's Motion to Dismiss will need to assess, *inter alia*, whether the claims of the '023 patent at issue in the instant Third Wave Suit are "patentably indistinct" from any of the claims of the First and Second Wave Patents—if they are, Azurity is precluded from bringing the instant Third Wave Suit. *SimpleAir*, 884 F.3d at 1167. Judge Stark, who has already ruled on the meaning and scope of the claims of the First Wave Patents (Shrestha Decl. Ex. G, Op. at 15-32), who found that Azurity failed to prove infringement of those patents and entered final judgment in Bionpharma's favor (*id*. at 52-72; Shrestha Decl. Ex. H, Final J.), and who dismissed with prejudice Azurity's Second Wave Suit (Shrestha Decl. Ex. O, JSD; Second Wave Suit, May 21, 2021 docket entry), is in the best position to assess Bionpharma's Motion to Dismiss. *Yang*, 409 F. Supp. 2d at 608-09; *Job Haines*, 936 F. Supp. at 233-34.

iii. Should Emergency Proceedings Be Necessary, Delaware Is the Best Forum to Resolve Them

Finally, should this suit proceed past the pleadings stage, emergency proceedings may be necessary, as Azurity alludes to in its Complaint. ECF No. 1, Compl. ¶¶ 29-32. As explained above, the parties have already fully briefed a PI motion Azurity filed in Delaware in connection with the Second Wave Suits. That briefing included thousands of pages of briefs, expert declarations, and documentary evidence, which is already before the Delaware court. Much of that briefing and evidence will have relevance to any preliminary injunction motion Azurity files in the instant Third Wave Suit—indeed, at least the irreparable harm briefing and evidence that would be submitted in the instant Third Wave Suit would be expected to be nearly identical to what was already filed in the Second Wave Suit.

The hearing for the Second Wave Suit PI motion was cancelled on April 28, 2021, the day before the April 29, 2021 hearing date. Second Wave Suits, ECF Nos. 58 and 92. It is at least

possible that Judge Stark considered some or all of those PI materials and is familiar with the evidence and arguments presented therein, much of which would need to be re-submitted in connection with any PI motion filed in the instant Third Wave Action. Thus, judicial economy would strongly favor Judge Stark resolving any PI motion filed by Azurity in the instant Third Wave Suit, as many of the arguments and evidence that will be submitted were already submitted and likely considered by Judge Stark in connection with the Second Wave Suit. *Yang*, 409 F. Supp. 2d at 608-09; *Job Haines*, 936 F. Supp. at 233-34.

c. Court Congestion Favors Transfer

It is indisputable that this Court is one of the busiest in the country. According to the latest Federal Court Management Statistics, this Court has 3,367 pending civil and criminal cases per judge. Shrestha Decl. Ex. U, Combined Civil and Criminal Federal Court Management Statistics - 12 Month Period Ending March 31, 2021. By contrast, Delaware has 630 civil and criminal cases pending per judge. Moreover, the average time to disposition in this Court for civil cases is 10.1 months, whereas in Delaware it is 7.3. *Id*. This factor also favors transfer to Delaware.

d. Delaware Has a Greater Local Interest in Deciding the Dispute[7]

While Bionpharma has an office in New Jersey, it resides in Delaware—as does Azurity. ECF No. 1, Compl. ¶¶ 2-4; *Valeant*, 978 F.3d at 1375. Further, the parties have been litigating Bionpharma's ANDA and Azurity's enalapril liquid patent family in Delaware for over the last two and a half years. Thus, Bionpharma respectfully submits that Delaware has a greater local interest in resolving this dispute than New Jersey, supporting transfer. *Yang*, 409 F. Supp. 2d at 609.

[7] The last two public interest factors—public policy of the fora and familiarity of the trial judge with the applicable state law in diversity cases—are inapplicable.

2. The Private Interest Factors Also Support Transfer

The private interest factors include:

> 1) the plaintiff's forum preference; 2) the defendant's forum preference; 3) where the claim arose; 4) the convenience of the parties as indicated by their relative physical and financial condition; 5) the convenience of the witnesses, but only to the extent they may be unavailable for trial in one of the fora; and 6) the location of books and records (similarly limited to the extent that they could not be produced in the alternative forum).

S. Jersey Gas, 2016 WL 266340, at *3 (quoting *Jumara*, 55 F.3d at 879)

a. Azurity's Choice of New Jersey Should Be Disregarded

As explained above in connection with the first-filed rule discussion, Azurity's original forum preference for this dispute was Delaware, and Azurity should be held to that original preference. Nevertheless, even if Azurity's choice of New Jersey for the instant Third Wave Suit is considered, that choice should be accorded less deference because Azurity did not sue in its home state. *Yang*, 409 F. Supp. 2d at 606; *Teva Pharm.*, 2017 WL 2269979, at *5. Thus, Bionpharma respectfully submits that this factor favors transfer to Delaware as that forum was Azurity's true first choice, and Azurity second choice of New Jersey should be afforded less deference because it is a foreign plaintiff.

b. Bionpharma's Choice of Delaware Supports Transfer

Bionpharma's preference for Delaware should be given weight for at least two legitimate reasons: (1) both Bionpharma and Azurity reside in Delaware; and (2) the over two and a half years of related litigation between the parties concerning the very ANDA and patent family at issue in the instant case. *See Abbott Labs v. Roxane Labs., Inc.*, C.A. No. 12-457-RGA-CJB, 2013 WL 2322770, at *19, *27 (D. Del. May 28, 2013) (§ 1404(a) movant's choice given weight where movant had presence in transferee forum and where activity concerning the subject matter of the suit took place in that transferee forum). Bionpharma believes that litigating in Delaware is simply

the most efficient way for the parties and the judiciary given that the parties have been litigating patent infringement actions concerning ANDAs for generic enalapril oral formulations for nearly the last five years,[8] and given Chief Judge Stark's extensive experience with and knowledge concerning Bionpharma's ANDA and Azurity's enalapril liquid patent family.

c. Where Claim Arose Slightly Weighs Against Transfer

Courts in this District have followed a "center of gravity" approach when assessing this factor in ANDA cases, focusing on where accused ANDA product was researched and developed and where the ANDA submission was prepared and filed from. *Teva Pharm.*, 2017 WL 2269979, at *6-*7. As the Delaware court found at trial in the First Wave Suits, Bionpharma's ANDA product was developed by CoreRx, Inc., a third-party contract manufacturer located in Florida. Shrestha Decl. Ex. G, Op. at 4, 8.[9] While the research and development of Bionpharma's ANDA product took place in Florida (not New Jersey), Bionpharma nevertheless concedes that its ANDA was prepared in and filed from Bionpharma's office in New Jersey. Thus, at best for Azurity, this factor slightly weighs against transfer. Nevertheless, Bionpharma respectfully submits that the other private and public interest factors at issue here strongly outweigh this factor.

d. Convenience of the Parties Slightly Favors Transfer

As explained above, both parties reside in Delaware, and both parties have been litigating the alleged infringement of Azurity's enalapril liquid patent family by Bionpharma's ANDA product in that forum for at least the last three years. Thousands of pages of documents regarding

[8] Prior to the filing of Bionpharma's ANDA and the First and Second Wave Suits, Azurity and Bionpharma were litigating in Delaware Bionpharma's ANDA for a generic version of Azurity's Epaned® Kit, a predecessor product to Epaned®. *Silvergate Pharm. Inc. v. Bionpharma Inc.*, C.A. No. 16-00876-MSG, ECF No. 1, Compl. (D. Del.). That case was resolved in 2018. *Id.* at ECF No. 286, Order of Dismissal.

[9] At the Court's invitation, Bionpharma will promptly submit a declaration attesting to the fact that CoreRx developed Bionpharma's ANDA product at its facilities in Florida.

Bionpharma's ANDA and ANDA product, Azurity's enalapril patent family, and the prior art are already before Chief Judge Stark in Delaware, either on the docket in the First and Second Wave Suits, or in Judge Stark's possession from trial. Thus, as a practical matter, Bionpharma submits that litigating in Delaware would be more convenient for the parties.

However, Bionpharma concedes that litigating in either this District or in Delaware would likely not be particularly inconvenient for either party given the parties' relative physical and financial condition. *Teva Pharm.*, 2017 WL 2269979, at *7. Thus, this factor is, at worst for Bionpharma, neutral.

e. Convenience of the Witnesses Is Neutral

Bionpharma knows of no witnesses that would be unavailable for trial in one of the fora. Thus, this factor is neutral. *Id*.

f. Location of Books and Records Is Neutral

As explained above in connection with other public and private interest factors, thousands of pages of documents regarding Bionpharma's ANDA and ANDA product, Azurity's enalapril patent family, and the prior art are already before Chief Judge Stark in Delaware, either on the docket in the First and Second Wave Suits, or in Judge Stark's possession from trial. Thus, as a practical matter, Bionpharma submits that the location of evidence supports transfer to Delaware.

Nevertheless, Bionpharma recognizes that this factor is considered "to the extent that the files could not be produced in the alternative forum." *Id*. at *5. Bionpharma does not dispute that both parties can produce documents in New Jersey; thus, this factor is neutral.

CONCLUSION

This lawsuit should never have been filed in this District. Azurity had already filed two previous waves of suits (three suits total) against Bionpharma in Delaware concerning the ANDA and patent family at issue in this Third Wave Suit. This is a clear instance of forum shopping, and

maintaining this Third Wave Suit here would be a gross waste of party and judicial resources, as explained above. Under the first-filed rule, Azurity should be held to its original first choice of Delaware. And transfer under 28 U.S.C. § 1404(a) is warranted: (1) the public interest factors overwhelmingly support transfer to Delaware, where Chief Judge Stark has extensive experience with the subject matter of the instant Third Wave Suit and is in the best position to rule on Bionpharma's pending Motion to Dismiss based on claim preclusion, and where at least three other related suits are currently pending; and (2) the private interest factors also support transfer because of Bionpharma's choice to move this case to Delaware, where both parties reside, and where substantial evidence that will be relevant to the claims and defenses in this case are already before the Delaware court.

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/s/ Thomas R. Curtin

Thomas R. Curtin
George C. Jones
McElroy, Deutsch, Mulvaney
& Carpenter, LLP
1300 Mount Kemble Ave.
P.O. Box 2075
Morristown, NJ 07962-2075
Tel: (973) 993-8100
Fax: (973) 425-0161
tcurtin@mdmc-law.com
gjones@mdmc-law.com

Of Counsel:

Andrew M. Alul
Roshan P. Shrestha, Ph.D.
Taft, Stettinius & Hollister LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
312-527-4000
aalul@taftlaw.com
rshrestha@taftlaw.com

Attorneys for Defendant
Bionpharma Inc.